

## 510(k) Summary of Safety and Effectiveness

1093511  
APR 16 2010

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

**Date Prepared:**

April 13, 2010

**Submitter's Information: 21 CFR 807.92(a)(1)**

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**Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)**

Product Name: Soring MBC200/BCC140  
Common Name: Electrosurgical cutting device  
Classification Name: electrosurgical cutting and coagulation device and accessories  
Class II, Product Code: GEI,  
Regulation: 21 CFR 878.4400

**Predicate Device: 21 CFR 807.92(a)(3)**

Device Classification Name	electrosurgical, cutting & coagulation & accessories
510(k) Number	K024059
Device Name	MBC SERIES
Applicant	SORING GMBH MEDIZINTECHNIK
Regulation Number	878.4400
Classification Product Code	GEI
Date Received	12/09/2002
Decision Date	01/08/2003
Decision	substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Reviewed by Third Party	No

**Device Description: 21 CFR 807.92(a)(4)**

Soring MBC200/BCC140 device has 2 configurations. Depending on the unit variant, the user can choose from the following functions:

- MBC200: Monopolar cutting and Coagulation and Bipolar Coagulation
- BCC140: Bipolar Cutting and Coagulation

Electrosurgical devices are frequently used during surgical operations helping to prevent blood loss in hospital operating rooms or in outpatient procedures. Electrosurgery is performed using an Electrosurgical Generator (also referred to as Power Supply or Waveform Generator) and a handpiece including one or several electrodes, sometimes referred to as an RF Knife. Lower RF-voltages (below 150) lead to a slower heat-up of the tissue, resulting in coagulation with no separation. Short RF-impulses with high voltage lead in a build-up of sparks together with a strong surface coagulation. During the use of the Soring MBC200/BCC140 device, power is transmitted via an electrode in the contact zone to tissue. When RF energy reaches a certain upper limit, an arc will occur at

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the contact zone of the active electrode to the tissue. This leads to a quick warm-up of the intercellular fluid. This vaporization of the intercellular fluid results into a burst of the cells and the tissue loses its cohesion, the electrode then cuts.

### Indications for Use: 21 CFR 807 92(a)(5)

The Soring MBC200/BCC140 devices are intended to cut and or coagulate (soft) biological tissue during surgical procedures. Typical users of this system are trained medical professionals.

### Contraindications:

Any use exceeding and/or deviating from the intended use of the device may lead to dangerous situations. Therefore: Use the device only in accordance with its intended purpose. Strictly adhere to all instructions provided in this operating manual. In particular, the device must not be used for any of the following purposes, as they are considered to be improper:

- Use during open-heart surgery,
- Use during eye surgery
- Monopolar use during neurosurgery
- Continuous operation,
- Use in direct combination with passive instruments (e.g. scalpels and forceps in contact with the active electrode),
- Use of incompatible or non-compliant accessories,
- Use of incompatible device combinations,
- Use of accessories whose rated voltage is not equal to the maximum output voltage of the device, and
- Use of the device close to a magnetic resonance tomograph (MRT)

### Technological Characteristics: 21 CFR 807 92(a)(6)

Technical characteristics for the subject device are described briefly in this section.

**Monopolar** - During monopolar application, the high-frequency current flows along the shortest distance from the active electrode, through the cross section of the patient's body, and to the neutral electrode.

**Bipolar** - During a bipolar application, the high-frequency current flows directly between two adjacent electrodes of the surgical instrument (e. g. legs of a pair of forceps). The current does not flow through the patient's body, but only through the area intended for the surgical application. Damage to the tissue is mostly avoided.

**Cutting (electrotomy)** - The high-frequency surgical device can be used to perform smooth cuts which are largely similar to those made with a common scalpel but cause only little blood flow thanks to the coagulating effect of the device.

- The cutting effect is achieved by the rapid, locally limited heating
- $>100^{\circ}\text{C}$  of the fluid inside and outside of the cells, which evaporates explosively and, thereby, bursts the tissue cells and cell connections.
- The active electrodes should have the smallest possible surface at the transition with the tissue.
- The quality of the cut varies with the cutting speed, the condition of the tissue and the current waveform.
- A low cutting speed or the use of a pulse-modulated high frequency current will lead to highly coagulated or scabbed cuts.
- The output necessary depends on the shape of the electrode and the tissue type. If the output is too low, the cells will not burst, and the tissue will stick to the electrode.
- If the output is too great, arcs may form between electrode and tissue and carbonize the cut surfaces.
- Electrotomy requires highly effective high-frequency voltage which is provided by the CUT output.

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Contact coagulation - If the electric current flowing from an electrode that is in contact with the tissue heats up the tissue to more than approx. 60°C, the extra and intracellular protein will coagulate.

- As the cells contract due to the fluid they lose, the cell walls will be fused together.
- The coagulation requires a lower effective high-frequency voltage which is supplied as pulse-modulated voltage from the COAG output.

The subject device is substantially equivalent to other legally marketed devices in the United States and functions in a manner similar and is intended for the same use as the predicate device.

### Brief summary of Non-clinical Tests and Results

Software verification and product validation tests were performed and meet the acceptance criterion. The subject device has been designed and tested to applicable safety standards (see below) and does not raise any new issues of safety, efficacy, or performance of the product.

Standard	Title
ISO 10993-1:1998	Biological Compatibility of medical devices – Part 1: Evaluation and Testing
EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
EN 60601-2-2	Medical electrical equipment - part 2-2: particular requirements for the safety of high frequency surgical equipment
EN ISO 14971	Medical devices – application of risk management to medical devices

### Conclusion: 21 CFR 807 92(b)(1)

The 510(k) for the MBC200/BCC140 device contains adequate information and data to enable FDA to determine substantial equivalence to the predicate device. The device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

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APR 16 2010

Re: K093511

Trade/Device Name: Soring MBC200/BCC140  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: March 25, 2010  
Received: April 8, 2010

Dear Mr. Schueller-Iwersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

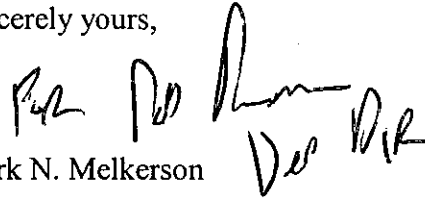
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K093511

Device Name: Soring MBC200/BCC140

Indications for Use:

The Soring MBC200/BCC140 devices are intended to cut and or coagulate (soft) biological tissue during surgical procedures.

Typical users of this system are trained medical professionals.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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